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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/554,252	01/18/2007	William C Sessa	YU/110	2742

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EXAMINER	
MERTZ, PREMA MARIA	
ART UNIT	PAPER NUMBER
1646	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/554,252	SESSA ET AL.	
	Examiner	Art Unit	
	Prema M. Mertz	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-54* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-54* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restriction

1. This application is a 371 of PCT/US04/12354. For applications filed under 371, PCT rules for lack of unity apply.

2. Restriction is required under 35 U.S.C. 121 and 372.

This application contains inventions or groups of inventions which are not so linked as to form a single inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1. Claims 1-10, 15-17, drawn to a composition comprising Nogo-B.

Group 2. Claims 11-14, drawn to a composition comprising Nogo-B antagonist, which is a monoclonal antibody.

Group 3. Claims 11-14, drawn to a composition comprising Nogo-B antagonist, which is an siRNA.

Group 4. Claims 11-14, drawn to a composition comprising Nogo-B antagonist, which is an antisense nucleic acid.

Group 5. Claims 11-14, drawn to a composition comprising Nogo-B antagonist, which is a ribozyme.

Group 6. Claims 11-14, drawn to a composition comprising Nogo-B antagonist, which is a soluble peptide.

Group 7. Claims 11-14, drawn to a composition comprising Nogo-B antagonist, which is a small molecule.

Group 8. Claims 18-22, 32, drawn to a nucleic acid encoding a Nogo-B protein, a vector, a host cell and a method for producing the protein.

Group 9. Claims 23-28, 30, 31, 33, drawn to an antagonist antibody to Nogo-B protein.

Group 10. Claims 23-27, 29-30, 31, 33, drawn to an agonist antibody to Nogo-B protein.

Group 11. Claims 34-37, drawn to a nucleic acid encoding an antibody to Nogo-B protein, a vector, a host cell and a method for producing the antibody.

Group 12. Claim 38, drawn to a method for detecting Nogo-B in a subject.

Group 13. Claims 39-41, drawn to a method for promoting angiogenesis in a subject by administering Nogo-B.

Group 14. Claims 42-43, drawn to a method for treating pathological vascular remodeling in a subject by administering Nogo-B.

Group 15. Claims 42-43, drawn to a method for preventing pathological vascular remodeling in a subject by administering Nogo-B.

Group 16. Claims 44-45, drawn to a method for promoting vascular quiescence in a subject by administering Nogo-B.

Group 17. Claims 46-47, 48, drawn to a method for inhibiting angiogenesis in a subject by administering Nogo-B antagonist.

Group 18. Claim 49, drawn to a method for reducing neointima formation in a blood vessel in a subject in need thereof comprising the step of administering Nogo-B.

Group 19. Claim 50, drawn to a method for inhibiting vascular injury-induced vascular narrowing or occlusion in a subject comprising the step of administering Nogo-B.

Group 20. Claim 51, drawn to a method for preventing vascular injury induced ischemia comprising the step of administering Nogo-B.

Group 21. Claim 52, drawn to a method for endothelial cell adhesion, spreading and migration comprising the step of contacting the cell with Nogo-B or a fragment thereof that retains a biological activity of Nogo-B.

Group 22. Claim 53, drawn to a method for inhibiting vascular smooth muscle cell migration comprising contacting the cells with Nogo-B or a fragment thereof that retains a biological activity of Nogo-B.

Group 23. Claim 54, drawn to a method for treating a subject suffering from a vascular injury comprising the step of administering a composition according to claim I.

NOTE: Applicants are advised that claim 12 is an improper Markush claim because the multiple elements recited therein are a monoclonal antibody, siRNA, an antisense nucleic acid, a ribozyme, a soluble peptide and a small molecule which do not share a common technical feature which is based on a common property or special technical feature not found in the prior art. These monoclonal antibody, siRNA, an antisense nucleic acid, a ribozyme, a soluble peptide and a small molecule are independent and distinct chemical compounds lacking either a common structural property which distinguishes them as group from structurally related compounds of the prior art or which provides them with a common utility which is lacking from those prior art monoclonal antibody, siRNA, an antisense nucleic acid, a ribozyme, a soluble peptide and a small molecule.

The inventions listed as Groups I-23 do not relate to a single general inventive concept under PCT Rule 13.1 because under PCT Rule 13.2 they lack the same or corresponding special technical feature for the following reasons:

The PCT rules define a special technical feature as a feature, which defines a contribution over the prior art. The first claimed invention fails to recite such a feature, since WO 00/60083 discloses a Nogo-B protein (see claims 11-14). The protein of the reference meets the limitations of the protein of Group I.

Since the first claimed invention lacks a special technical feature, the other claimed inventions cannot share a special technical feature with the first claimed invention. The inventions of Group 1 are patentably distinct from the product of Group 8 because the product of Group 1 can be synthesized by materially different methods, such as by chemical synthesis or isolated from nature. The inventions of Groups 1, 8, 9-11 are patentably distinct from the products of Groups 2-7 because the products of Groups 1, 8, 9-11 can be used in methods that are materially different from the methods in which the inventions of Groups 2-7 are used. The methods of Groups 12-23 are patentably distinct from each other because each recites method steps not required by the other, each method uses different starting materials, patient populations and the search of all methods in one patent application would result in an undue search burden.

2. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. 1.48(b) and by the fee required under 37 C.F.R. 1.17(h).

Election of species

3. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

If Group I is elected, Applicants must elect a species of additional components recited in claim 7

If Group I is elected, Applicants must elect a species of additional compound recited in claim 17.

If any one of Groups 2-7 are elected, Applicants must elect a species of additional components recited in claim 13.

If any one of Groups 9-10 is elected, Applicants must elect a species of additional components recited in claim 31.

If Group 13 is elected, Applicants must elect a species of condition recited in claim 41.

If any one of Groups 13-14 are elected, Applicants must elect a species of condition recited in claim 43.

If Group 16 is elected, Applicants must elect a species of condition recited in claim 48.

The following claim(s) are generic: 1-6, 9-10, 11, 14, 15-30, 32-40, 42, 44-47.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: they are structurally and functionally distinct compounds and therefore cannot constitute a unifying technical feature.

Claim rejoinder

4. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35

U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process

claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Prema Mertz whose telephone number is (571) 272-0876. The examiner can normally be reached on Monday-Friday from 7:00AM to 3:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, can be reached on (571) 272-0835.

Official papers filed by fax should be directed to (571) 273-8300. Faxed draft or informal communications with the examiner should be directed to (571) 273-0876.

Information regarding the status of an application may be obtained from the Patent application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Prema Mertz/
Primary Examiner
Art Unit 1646